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K090234

Spectra-System Dental Implants 2008
Traditional 510(K) Submission

510(K) Summary (21CFR 807.92(a))

MAY 15 2009

1. **Submitter's Information**
Company Name: Implant Direct LLC
Address: 27030 Malibu Hills Rd., Calabasas Hills, CA USA 91301
Telephone Number: 818-444-3300
Fax Number: 818-444-3400
Registration Number: 3001617766
Contact Person: Tom Gottenbos
Date Summary Prepared: October 13, 2008
Classification Name: Implant, Dental, Endosseous
Common/Usual Name: Endosseous Dental Implant

2. **Device Trade Name:** Spectra-System Dental Implants 2008

3. **Predicate Device(s):** Implant Direct LLC Spectra-System (K061319), Implant Direct LLC ReActive Dental Implant System (K080713), Implant Direct LLC Legacy Implants With HA Coating (K073033)

4. **Device Description:**
The Spectra-System Dental Implants 2008 system consists of implants, abutments, healing components, and screws for use in one or two-stage placement and restorations.

5. **Intended Use:**
The Spectra-System Dental Implant 2008 system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The Dental Implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single-tooth or multiple-tooth restorations, recognizing bone stability and appropriate occusal load requirements.

6. **Device Comparison:**
This submission is comprised of devices whose physical dimensions, material composition, indications for use and methods of manufacture were previously approved and have the same principles of operation as the cited predicate devices. The differences between the components included in this submission and their predicate devise pose no new or additional issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Mr. Thomas Gottenbos
VP of IT/Regulatory Affairs
Implant Direct LLC
27030 Malibu Hills Road
Calabasas Hills, California 91301

Re: K090234
Trade/Device Name: Spectra-System Dental Implants 2008
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 11, 2009
Received: May 13, 2009

Dear Mr. Gottenbos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1071

K090234

Indications for Use

510(k) Number (if known): K090234

Device Name: Spectra-System Dental Implants 2008

Indications for Use:

Spectra-System Dental Implants 2008 are comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single-tooth or multiple-tooth restorations, recognizing bone stability and appropriate occusal load requirements.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090234